IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NUMBER:

10/660,122

FILING DATE:

09/11/2003

FIRST NAMED INVENTOR:

David J. Ecker

ART UNIT:

1637

EXAMINER NAME:

Jeffrey Norman Fredman

ATTORNEY DOCKET NUMBER:

DIBIS-0002US.P3 (10450)

TITLE:

METHOD FOR RAPID IDENTIFICATION

OF PATHOGENS IN HUMANS AND

ANIMALS

MAIL STOP AMENDMENT COMMISSIONER FOR PATENTS P.O. BOX 1450 ALEXANDRIA, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT Under 37 C.F.R. §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 C.F. R. §§ 1.56 and 1.97-98, enclosed herewith is PTO Forms PTO/SB/08A and PTO/SB/08B listing references for consideration by the Examiner.

Documents disclosed herein are those compiled from United States Patent

Applications related to the instant application. Examiner has already considered many of
these documents in the related cases in which they were filed.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:
multiply within three months of the filing date of the application, or date of entry into
the national stage of an international application, or before the mailing date of a
first office action on the merits, whichever event last occurred;
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continued examination (RCE) under 37 C.F.R. § 1.114;
after three months of the filing date of this national application or the date of
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of the first official action on the merits, whichever event last occurred, but before
that mailing date of the first office action to occur of either: (1) a final action
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application, and:
attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for
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Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that:
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foreign patent office in a counterpart foreign application not more
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knowledge of the person signing this certification after making
reasonable inquiry, no item of information contained in this
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§ 1.56(c) more than three months prior to the filing of this
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on or before the payment of the issue fee but after the mailing date of the first
to occur of either: (1) a final action under 37 C.F.R. § 1.113; (2) a notice of

allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application, and: Applicant certifies pursuant to 37 C.F.R. § 1.97(e) that: each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement; OR no item of information contained in this Information Disclosure Statement was cited in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Statement, AND attached hereto is the fee set forth under 37 C.F.R. § 1.17(p) for submission of this Information Disclosure Statement under 37 C.F.R. § 1.97(c); OR after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 C.F.R. § 1.97(i), although the information may not be considered by the USPTO. Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose. This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. , filed on , and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 C.F.R. § 1.98(d). This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 C.F.R. § 1.98(a)(2)(i), copies of each U.S. Patent and each

Serial No.: 10/660,122 Docket No.: DIBIS-0002US.P3

U.S. Patent Application Publication are not required to be submitted. Copies of any
foreign patent documents and non-patent literature cited herein are enclosed.
☐ Each item of information contained in this Information Disclosure Statement was
cited in the communication from a foreign patent office in a counterpart application, and
the communication was not received by any individual designated in 37 C.F.R. § 1.56(c)
more than thirty days prior to the filing of this Information Disclosure Statement 37
C.F.R. § 1.704(d).
Applicant submits that no fee is required for the consideration of this Information
Disclosure Statement. However, if a fee is due, the Commissioner is hereby authorized
to charge Deposit Account No 500252 referencing case number DIBIS-0002US.P3.
Consideration of the listed references and favorable action are solicited.
Respectfully submitted,
Dated: 1-20 21, 2007
Jeffrey L'ardes, Esq.

Registration No.: 55,355
Isis Pharmaceuticals, Inc.
1896 Rutherford Road
Carlsbad, CA 92008

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Substitute	for form 1449/PTO				Complete if Known
INFORMATION DISCUSSION				Application Number	10/660,122
INFO	INFORMATION DISCLOSURE		Filing Date	09/11/2003	
STAT	STATEMENT BY APPLICANT		First Named Inventor	David J. Ecker	
			Art Unit	1637	
	(Use as many she	ets as	necessary)	Examiner Name	Jeffrey Norman Fredman
Sheet	1	of	11	Attorney Docket Number	DIBIS-0002US.P3

			U.S. PATENT I	OCUMENTS	
Examiner Initials *	Cite No.1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	CQ	US-5,484,908	01-16-1996	Froehler et al.	- · · · · · · · · · · · · · · · · · · ·
	CR	US-5,502,177	03-26-1996	Matteucci et al.	
	CS	US-5,503,980	04-02-1996	Cantor	
	CT	US-5,527,675	06-18-1996	Coull et al.	
	CU	US-5,580,733	12-03-1996	Levis et al.	
	CV	US-5,625,184	04-29-1997	Vestal et al.	
	CW	US-5,645,985	07-08-1997	Froehler et al.	, , <u></u>
	CX	US-5,686,242	11-11-1997	Bruice et al.	
	CY	US-5,700,642	12-23-1997	Monforte et al.	
	CZ	U\$-5,759,771	06-02-1998	Tilanus	
	DA	US-5,763,588	07-09-1998	Matteucci et al.	
	DB	US-5,770,367	06-23-1998	Southern et al.	
	DC	US-5,777,324	07-07-1998	Hillenkamp	
	DD	US-5,830,653	11-03-1998	Froehler et al.	
	DE	US-5,830,655	11-03-1998	Monforte et al.	
	DF	US-5,851,765	12-22-1998	Koster	
	DG	US-5,864,137	01-26-1999	Becker et al.	
	DH	US-5,869,242	02-09-1999	Kamb	
	DI	US-5,871,697	02-16-1999	Rothberg et al.	
	DJ	US-5,876,936	03-02-1999	Ju	
	DK	US-5,928,906	07-27-1999	Koster et al.	

	FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,				
Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	۳			
	DL	DE19802905	07-29-1999	Bruker Daltonik					
	DM	DE19824280	12-02-1999	Bruker Daltonik					
	DN	DE19852167	05-31-2000	Bruker Saxonia					
	DO	EP1138782	10-14-2001	Bruker Saxonia					
	DP	EP1234888	08-28-2002	Bruker Saxonia					
	DQ	EP1333101	08-06-2003	Bruker Daltonik					
	DR	GB2325002	11-11-1998	Bruker Franzen					
	DS	GB2339905	02-09-2000	Bruker Daltonik					
	DT	WO 93/03186	02-18-1993	Hoffman-La Roche					
	DU	WO 94/16101	07-21-1994	Koster					

Examiner Signature	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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STA	STATEMENT BY APPLICANT			First Named Inventor	David J. Ecker
				Art Unit	1637
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Sheet	2	of	11	Attorney Docket Number	DIBIS-0002US.P3

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Initials *	No.1	Number - Kind Code ² (if known)	MM-DD-YYYY		Passages or Relevant Figures Appear
	DV	US-5,981,176	11-09-1999	Wallace	
	DW	US-5,994,066	11-30-1999	Bergeron et al.	
	DX	US-6,001,564	12-14-1999	Bergeron et al.	-
	DY	US-6,005,096	12-21-1999	Matteucci et al.	
	DZ	US-6,007,992	12-28-1999	Lin et al.	
	EA	US-6,028,183	02-22-2000	Lin et al.	
	EB	US-6,043,031	03-28-2000	Koster et al.	
	EC	US-6,046,005	04-04-2000	Ju et al.	
	ED	US-6,051,378	04-18-2000	Monforte et al.	
	EE	US-6,054,278	04-25-2000	Dodge et al.	
•	EF	US-6,074,823	06-13-2000	Koster	
	EG	US-6,090,558	07-18-2000	Butler et al.	• "-
	EH	US-6,104,028	08-15-2000	Hunter et al.	- "
	EI	US-6,111,251	08-29-2000	Hillenkamp	
	EJ	US-6,140,053	10-31-2000	Koster	
	EK	US-6,146,144	11-14-2000	Fowler et al.	
	EL	US-6,153,389	11-28-2000	Haarer et al.	
	EM	US-6,159,681	12-12-2000	Zebala	,
	EN	US-6,180,372	01-30-2001	Franzen	, ,
	EO	US-6,194,144	02-27-2001	Koster	

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	Cita	Foreign Patent Document	Dublication	Name of Patentee or	Pages, Columns, Lines,			
Examiner Initials*	Cite No. 1 Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) Publication Date MM-DD-YYYY	Date	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T 6			
• .	EP	WO 94/21822	09-24-1994	Koster				
	EQ	WO 96/29431	09-26-1996	Sequenom				
	ER	WO 96/32504	10-17-1996	Trust. of Boston				
	ES	WO 96/37630	11-28-1996	SRI International	'-			
•	ET	WO 98/03684	01-29-1998	Hybridon Inc.				
	EU	WO 98/12355	03-26-1998	Genetrace Sys.				
	EV	WO 98/14616	04-09-1998	Perseptive Bio.				
	EW	WO 98/15652	04-16-1998	Brax Genomics				
	EX	WO 98/20020	05-14-1998	Sequenom Inc.				
	EY	WO 98/20157	05-14-1998	Infectio Diagnost.				
	EZ	WO 98/26095	06-18-1998	Genetrace Sys.				

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INFC	RMATION	DIS	CLOSURE	Filing Date	09/11/2003
STA	STATEMENT BY APPLICANT		First Named Inventor	David J. Ecker	
				Art Unit	1637
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Sheet	3	of	11	Attorney Docket Number	DIBIS-0002US.P3

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Evaminas	Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevan				
Examiner Initials *	No.1	Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear				
	FA	US-6,197,498	03-06-2001	Koster					
	FB	US-6,218,118	04-17-2001	Sampson et al.					
	FC	US-6,221,587	04-24-2001	Ecker et al.					
	FD	US-6,221,601	04-24-2001	Koster et al.					
	FE	US-6,221,605	04-24-2001	Koster					
•	FF	US-6,225,450	05-01-2001	Koster					
	FG	US-6,235,476	05-22-2001	Bergmann et al.					
	FH	US-6,235,478	05-22-2001	Koster					
	FI	US-6,235,480	05-22-2001	Shultz et al.					
	FJ	US-6,238,871	05-29-2001	Koster					
	FK	US-6,238,927	05-29-2001	Abrams et al.					
	FL	US-6,258,538	07-10-2001	Koster et al.					
	FM	US-6,265,716	07-24-2001	Hunter et al.					
•	FN	US-6,268,129	07-31-2001	Gut et al.	-				
	FO	US-6,268,131	07-31-2001	Kang et al.					
	FP	US-6,268,146	07-31-2001	Shultz et al.	-				
	FQ	US-6,270,973	08-07-2001	Lewis et al.					
	FR	US-6,270,974	08-07-2001	Shultz et al.					
	FS	US-6,277,573	08-21-2001	Koster					
	FT	US-6,277,578	08-21-2001	Shultz et al.					

		FOREIGN PA	TENT DOCU	MENTS		
Examiner Cite	Cite	Foreign Patent Document	ent Document Publication	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶
	FU	WO 98/31830	07-23-1998	Brax Genomics		
	FV	WO 98/40520	09-17-1998	Hybridon Inc.		
	FW	WO 99/05319	02-04-1999	Rapigene, Inc.		
	FX	WO 99/29898	06-17-1999	Max-Planck		
	FY	WO 99/57318	11-11-1999	Sequenom Inc.		
	FZ	WO 01/07648	02-01-2001	Artus Gesell.		
*	GA	WO 01/23604	04-05-2001	Infectio Diagnost.		
	GB	WO 01/32930	05-10-2001	California Instit.		
	GC	WO 01/51661	07-19-2001	Amsterdam Support		
	GD	WO 01/57263	08-09-2001	Advion Biosci.		

^{*} A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is too voluminous and easily obtainable by the Examiner.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449/PTO Complete if Known 10/660,122 Application Number INFORMATION DISCLOSURE Filing Date 09/11/2003 STATEMENT BY APPLICANT First Named Inventor David J. Ecker Art Unit 1637 (Use as many sheets as necessary) Examiner Name Jeffrey Norman Fredman Sheet of 11 4 **DIBIS-0002US.P3** Attorney Docket Number

			U.S. PATENT I	OCUMENTS		
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Page Calcard Line Miles Bullet	
Initials *	No.1	Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	GE	US-6,300,076	10-09-2001	Koster		
	GF	US-6,312,893	11-06-2001	Van Ness et al.		
	GG	US-6,312,902	11-06-2001	Shultz et al.		
	GH	US-6,361,940	03-26-2002	Van Ness et al.		
	GI	US-6,372,424	04-16-2002	Brow et al.		
	GJ	US-6,391,551	05-21-2002	Shultz et al.		
	GK	US-6,423,966	07-23-2002	Hillenkamp et al.		
	GL	US-6,428,955	08-06-2002	Koster et al.		
	GM	US-6,432,651	08-13-2002	Hughes et al.		
	GN	US-6,436,635	08-20-2002	Fu ct al.		
	GO	US-6,436,640	08-20-2002	Simmons et al.		
	GP	US-6,458,533	10-01-2002	Felder et al.		
,	GQ	US-6,468,748	10-22-2002	Monforte et al.		
	GR	US-6,475,736	11-05-2002	Stanton, Jr.		
	GS	US-6,479,239	11-12-2002	Anderson et al.		
	GT	US-6,500,621	12-31-2002	Koster		
	GU	US-6,558,902	05-06-2003	Hillenkamp		
	GV	US-6,566,055	05-20-2003	Monforte et al.		
	GW	US-6,582,916	06-24-2003	Schmidt et al.		
	GX	US-6,589,485	07-08-2003	Koster		

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Examiner Initials*	Cite	Foreign Patent Document	Foreign Patent Document Publication		Pages, Columns, Lines,	
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	GY	WO 02/10186	02-07-2002	California Instit.		
	GZ	WO 02/18641	03-07-2002	Sequenom-Gemini		
	HA.	WO 02/21108	03-14-2002	Large Scale		
	HB	WO 02/50307	06-27-2002	Chugai Seiyaku		
	HC	WO 02/57491	07-25-2002	Board of Trustees of the Leland		
	HD	WO 02/077278	10-03-2002	Council of Scientific		
	HE	WO 02/099034	12-12-2002	Infection Diagnostic		
	HF	WO 03/002750	01-09-2003	High Throughput		
	HG	WO 03/008636	01-30-2003	Infectio Diagnost,		
	НН	WO 03/016546	02-27-2003	Flinders Technol.	-	_

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Initials *	No.1	Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear
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	Cite No. ¹	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵			
	JJ	WO 03/060163	07-24-2003	Keygene N.V.					
	ЛΚ	WO 03/088979	10-30-2003	Centre National					
	几	WO 03/097869	11-27-2003	Con/Cipio GmbH					

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	ЈМ	BAHRMAND, A. R. et al., "Use of restriction enzyme analysis of amplified DNA coding for the hsp65 gene and polymerase chain reaction with universal primer for rapid differentiation of mycobacterium species in the clinical laboratory," Scand. J. Infect. Diseases (1998) 30(5):477-80.	
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	JY	DIAS NETO, E. et al., "Shotgun sequencing of the human transcriptome with ORF expressed sequence tags," PNAS (2000) 97(7):3491-3496.	
	JZ	DINAUER, D. M. et al., "Sequence-based typing of HLA class II DQB1," Tissue Antigens (2000) 55(4):364-368.	
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INEO		DIG	CLOCUDE	Application Number	10/660,122	
INFORMATION DISCLOSURE				Filing Date	09/11/2003	
SIAI	FWFNI R	YA	PPLICANT	First Named Inventor	David J. Ecker	
				Art Unit	1637	
(Use as many sheets as necessary)			necessary)	Examiner Name	Jeffrey Norman Fredman	
Sheet	8	of	11	Attorney Docket Number	DIBIS-0002US.P3	

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	KW	MORSE, R. et al., "Nucleotide Sequence of Part of the <i>ropC</i> Gene Encoding the β' Subunit of DNA-Dependent RNA Polymerase from some Gram-Positive Bacteria and Comparative Amino Acid Sequence Analysis," <i>System Appl. Microbiol.</i> (1996) 19:150-157.	
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INFORMATION DISCLOSURE					Filing Date	09/11/2003	
	STATEMENT BY APPLICANT				First Named Inventor	David J. Ecker	
					Art Unit	1637	
	(Use as many sheets as necessary)				Examiner Name	Jeffrey Norman Fredman	
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	LK	SCHRAM, K. H., "Mass Spectrometry of Nucleic Acid Components," Biomedical Applications of Mass Spectrometry (1990) 34:203-280.	
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			CLOSURE	Filing Date	09/11/2003	
STAT	EMENT B	YA	PPLICANT	First Named Inventor	David J. Ecker	
				Art Unit	1637	
(Use as many sheets as necessary)			necessary)	Examiner Name	Jeffrey Norman Fredman	
Sheet	11	of	11	Attorney Docket Number	DIBIS-0002US.P3	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	LU	WELHAM, K. J. et al., "The Characterization of Micro-organisms by Matrix-assisted Laser Desorption/Ionization Time-of-flight Mass Spectrometry," <i>Rapid Commun. Mass Spec.</i> (1988) 12:176-180.	
	LV	WIDJOJOATMODJO, M. N. et al., "Rapid identification of bacteria by PCR-single-strand conformation polymorphism," J. Clin. Microbiol. (1994) 32(12):3002-3007.	
	LW	WOLTER, A. et al., "Negative Ion FAB Mass Spectrometric Analysis of Non-Charged Key Intermediates in Oligonucleotide Synthesis: Rapid Identification of Partially Protected Dinucleoside Monophosphates," Biomed. Environ. Mass Spectrom. (1987) 14:111-116.	
	LX	WOO, T. H. S. et al., "Identification of Leptospira inadai by continuous monitoring of fluorescence during rapid cycle PCR," Systematic and Applied Microbiology (1998) 21(1):89-96.	
	LY	WUNSCHEL, D. et al., "Discrimination among the B. cereus group, in comparison to B. subtilis, by structural carbohydrate profiles and ribosomal RNA spacer region PCR," Systematic and Applied Microbiology (1994) 17(4):625-635.	
	LZ	WUNSCHEL, D. S. et al., "Analysis of double-stranded polymerase chain reaction products from the Bacillus cereus group by electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," <i>Rapid Communications in Mass Spectrometry</i> (1996) 10(1):29-35.	
	MA	YASUI, T. et al., "A specific oligonucleotide primer for the rapid detection of Lactobacillus lindneri by polymerase chain reaction," <i>Can. J. Microbiol.</i> (1997) 43(2):157-163.	
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Examiner	 Date	
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

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